

## REMARKS

Attached hereto is a marked-up version of the changes made to the claims by the above amendment. The attached page is captioned “**Version with markings to show changes made.**”

Claims 10 and 11 have been amended to use alternate language for the subject matter encompassed by the claim. No change in claim scope is intended or has occurred.

No new matter has been introduced, and entry of the amendments is respectfully requested.

### ***Rejection under 35 U.S.C. § 112***

Claims 10 and 11 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite due to the use of a parenthesis.

Claims 10 and 11 have been amended to use alternate language to represent dosages presented in the claims as an abbreviation of milligrams of photosensitizer per square meter of body surface area of a subject as recited in claims 1, 3, and 9, from which claims 10 and 11 depend. The parenthesis has been removed, and Applicants request the withdrawal of the instant rejection.

### ***Prior art rejection under 35 U.S.C. § 103***

Claims 1-20 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Levy et al. (USP 5,798,349). Applicants have carefully reviewed the statement of the rejection as well as the cited reference and understand the rejection to be based upon the assertion of obviousness “to determine the appropriate interval for administration” of a photosensitizer.

Applicants thus believe that the rejection is alleging a *prima facie* case of “obvious to optimize” the photodynamic therapy (PDT) methods of Levy et al. with respect to the interval for PDT treatment.

This particular issue is informed by MPEP 2144.05 II. and the cases therein. In particular, MPEP 2144.05 II.B. sets forth the standard that “Only Result-Effective Variables Can Be Optimized”. That subsection states as follows:

“A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.”

Applicants respectfully point out that the parameter of more frequent PDT treatment within the first three months following an initial PDT treatment was expressly identified as *not result effective* by Schmidt-Erfurth et al. (Arch. Ophthalmol. 117:1177-1187 (1999)) with respect to long term outcome in choroidal neovasculture (CNV). A copy of this reference was provided with the IDS filed December 27, 2002 and a copy is attached hereto for the Examiner's convenience.

Schmidt-Erfurth et al. teach the administration of a PDT retreatment at intervals of from 2 to 4 weeks after an initial treatment (see page 1178, sections entitled “Retreatment Protocol” and “Photodynamic Therapy”). The retreatment protocols were termed regimens 2 and 4 as shown in Table 2 on page 1179. On page 1183, right column second full paragraph, Schmidt-Erfurth et al. state that

“In summary, there was no obvious difference in the effects induced by regimen 2 or regimen 4. Absence of leakage was frequent at an early stage, and reappeared continuously thereafter in both groups. *Neither regimen achieved a higher rate of long-term complete absence of leakage in classic CNV than that of a single treatment.*” (*emphasis added*).

This conclusion is noted in the instant application in the paragraph bridging pages 3 and 4 of the specification. Therefore, retreatment within the three or six months following an initial PDT treatment was observed by Schmidt-Erfurth et al. to **not** be result effective. Accordingly, optimization of the interval for retreatments during the three or six months following an initial PDT treatment is not *prima facie* obvious.

Stated differently, there would have been no expectation that retreatments at about 45 days as encompassed by the instant claims would have an effect on the result of the methods disclosed by Levy et al. or even Schmidt-Erfurth et al. Absent such an expectation, the claims cannot have been obvious at the time of the invention. Accordingly, this rejection may be properly withdrawn.

### Conclusion

In light of the above amendments and discussion, Applicants respectfully submit that the claims are in condition for allowance and urge early indication to that effect.

The Examiner is encouraged to contact the undersigned to expedite prosecution of the instant application.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012012100.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Kindly amend the claims as follows:

10. (amended)      The method of claim 9, wherein the PS is administered at a concentration ranging between about 2 to 8 mg[/ $\text{m}^2$  (~~PS/body surface area of subject~~)] PS per square meter of body surface area of said subject.

11. (amended)      The method of claim 10, wherein the PS is administered at a concentration of 6 mg[/ $\text{m}^2$ ] PS per square meter of body surface are of said subject.